REMARKS

The foregoing amendments and the following remarks are submitted with regard and reference to the communication dated July 29, 2003.

Status of the Claims

Claims 14-17 are pending in the application. Claims 4, 6, 7 and 18-32, which are withdrawn from consideration, and claims 1-3, 5 and 8-13 were cancelled, without prejudice, in Applicants' amendment filed on May 20, 2003. Claims 14 and 15 have now been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. Support for the amended claims can be found generally through Applicants' specification.

Claim Objections

The Examiner has objected to Claim 15 because the word "likestem" is recited and should read "like stem". Applicants have above amended Claim 15 and request that this objection be withdrawn.

The §103 Rejection

The Examiner has maintained the rejection of Claims 14-17 under 35 U.S.C. 103(a) as being unpatentable over Pittenger *et al* [Science 284:143-147, 2 April 1999] in view of Sambrook *et al.* [Molecular Cloning, Book 3, 1989]. The Examiner remarks that Pittenger teach mesenchymal stem cells which are capable of differentiation into multiple mesenchymal lineages and as such, Pittenger teach pluripotent stem cells, as required by the claims. The Examiner remarks that Claim 15 is a product-by-process claim and asserts that even though product-by-process claims are limited and defined by the process, determination of patentability is based on the product itself, and, the Examiner asserts, Pittenger teaches the stem cell product. The Examiner takes the position that the Specification does not define the claimed cells in such a way

that they would be distinguished from other pluripotent stem cells known in the art. In particular, the Examiner remarks that "there is no requirement in the claims for the cells to differentiate into all three of these lineages", referring to endodermal, ectodermal and mesodermal lineages, and as such, any teaching which shows differentiation into any one of these lineages would anticipate the claims, particularly referring to Claim 14. Following this line of argument, the Examiner then asserts that, in view of the combined teachings of Pittenger and Sambrook, it would have been obvious for one of ordinary skill in the art at the time the claimed invention was made, to use the mesenchymal stem cells, which are found to differentiate into multiple mesenchymal lineages *in vitro*, as taught by Pittenger, and transfect them with any DNA of interest, as taught by Sambrook, with a reasonable expectation of success. Applicants respectfully disagree and assert that the combination of references of Pittenger and Sambrook does not make obvious the invention claimed in Claims 14-17, and in particular does not make obvious the product itself. Applicants submit that any teaching which shows differentiation into one of the endodermal, ectodermal or mesodermal lineages does not anticipate the stem cells of Applicants, which are capable of differentiation to cells of any of endodermal, ectodermal and mesodermal lineages and does not anticipate or make obvious the instant claims, particularly as amended. The Specification provides extensive teaching and specific examples that define and characterize the novel pluripotent embryonic-like stem cells of Applicants as distinct from any other pluripotent stem cells known in the art. In fact, the claimed pluripotent embryonic like stem cells are uniquely capable of differentiating into cells of each and any of the endodermal, ectodermal or mesodermal lineages. For clarification of this unique characteristic, which is described and supported by teaching in the Specification, Applicants have above amended Claims 14 and 15 to more clearly characterize the cells by this capacity. The Claims as now presented include this appropriate characteristic and require that the claimed cells be capable of differentiating into all three of the endodermal, ectodermal and mesodermal lineages. Pittenger teaches mesenchymal stem cells, which are found to differentiate into multiple mesenchymal lineages *in vitro*. These mesenchymal stem cells only differentiate into cells of a single lineage, the mesodermal lineage do not anticipate the stem cells of Applicants. Further, the combination of Pittenger with Sambrook, which it is asserted teaches transfect of stem cells with any DNA of

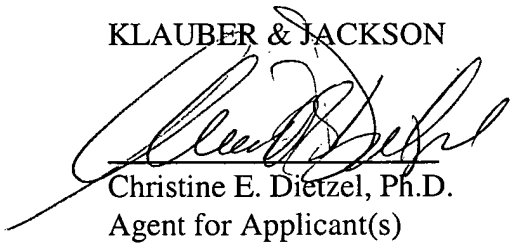
interest, does not make obvious transfection of the novel pluripotent embryonic-like stem cells of the invention. In as much as these stem cells are novel, the transfection thereof to generate genetically engineered pluriotent embryonic-like stem cells is novel and non-obvious.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 103 rejection is obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,
KLAUBER & JACKSON



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Complete Listing of Claims in Application U.S.S.N. 09/668,508

Claims 1-13 (cancelled)

14. (presently amended) A pluripotent embryonic-like stem cell, derived from non-embryonic or postnatal animal cells or tissue, capable of self-renewal and capable of differentiation to cells of any of endodermal, ectodermal and mesodermal lineages, genetically engineered to express a gene or protein of interest.

15. (presently amended) A method of producing a genetically engineered pluripotent embryonic-like stem ~~embryonic-likestem~~ cell comprising the steps of:

(a) transfecting pluripotent embryonic-like stem cells, derived from non-embryonic or postnatal animal cells or tissue, capable of self-renewal and capable of differentiation to cells of any of endodermal, ectodermal and mesodermal lineages, with a DNA construct comprising at least one of a marker gene or a gene of interest;

(b) selecting for expression of the marker gene or gene of interest in the pluripotent embryonic-like stem cells;

(c) culturing the stem cells selected in (b).

16. (original) A genetically engineered pluripotent embryonic-like stem cell produced by the method of claim 15.

17. (original) The stem cell of claim 16 which is a human cell.

Claims 18-32 (cancelled)